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FEDERAL BUREAU OF INVESTIGATION

Date of transcription 07/02/2008

On July 1, 2008, ARNOLD KLEIN, medical doctor, white male, born February 27, 1945, telephone number 310-275-5136, office address 435 N. Roxbury Drive, Suite 204, Beverly Hills, California 90210, contacted the writer by telephone. After being advised of the identity of the interviewing Agent and the purpose of the interview, DR. KLEIN provided the following information:

DR. KLEIN advised he was scheduled to teach a Continuing Medical Education (CME) course for MILLENIUM CME INSTITUTE, INC. (MILLENIUM) in two weeks (07/14/2008). DR. KLEIN advised MILLENIUM is funded by ALLERGAN through unrestricted educational grants. DR. KLEIN provided MILLENIUM's website as: www.thederm.org

DR. KLEIN advised he wanted to speak at the course about the truth about BOTOX by using the literature that is available. DR. KLEIN advised no other physicians were cancelled, just him. DR. KLEIN felt MILLENIUM had cancelled him at the direction of ALLERGAN over concerns of what he might say. DR. KLEIN felt that ALLERGAN should not have any say in who speaks at a CME course because the grant money is unrestricted and the CME company (MILLENIUM) can do whatever they want with it. DR. KLEIN advised at his last CME course in Las Vegas, Nevada an ALLERGAN person sat in on his talk because they were concerned about what he might say. DR. KLEIN advised he was told by MILLENIUM that they were going to use "Web-inars" instead of him. DR. KLEIN explained a web-inar to be an internet based seminar. DR. KLEIN believes the purpose of CME courses is for physicians to share information, good and bad, and if companies are filtering out the bad, then it is a problem.

DR. KLEIN was asked about the recent article in the AMERICAN ACADEMY OF NEUROLOGY, which stated that, "BoNT is probably ineffective in episodic migraine and chronic tension-type headache (Level B). There is presently no consistent or strong evidence to permit drawing conclusions on the efficacy of BoNT in chronic daily headache (mainly transformed migraine) (Level U)." DR. KLEIN advised he had seen the article and stated that BOTOX worked for headache and he was sure of it, but the problem is that ALLERGAN is promoting it without it being approved by the Food and Drug Administration (FDA). DR. KLEIN advised the treatment is very technique specific and many physicians are not skilled enough to have positive results.

Investigation on 07/01/2008 at Atlanta, Georgia (telephonically)
File # 209A-AT-102189 - 121 Date dictated 07/02/2008
by SA

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DR. KLEIN provided the names of three (3) individuals that would be helpful with the governments investigation: [redacted] [redacted] who DR. KLEIN advised is very honest, [redacted] who would tell everything he knew and [redacted] who was fired by ALLERGAN at the same time as DR. KLEIN.

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FEDERAL BUREAU OF INVESTIGATION

Date of transcription 04/28/2008

On April 22, 2008, ARNOLD KLEIN, medical doctor, white male, born February 27, 1945, cellular telephone number 310-721-5550, office address 435 N. Roxbury Drive, Suite 204, Beverly Hills, California 90210, was interviewed with his attorney [REDACTED] at his office located at 10250 Constellation Boulevard, Los Angeles, California 90067, telephone number 310-553-3000. Also present for the interview were [REDACTED] DR. KLEIN's assistant and Assistant United States Attorney (AUSA), [REDACTED]. After being advised of the identities of the interviewing Agents and the purpose of the interview, DR. KLEIN provided the following information:

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DR. KLEIN advised he had been injecting fillers for lip enhancements since 1989 and he had been injecting collagen since 1997. DR. KLEIN remembered when BOTOX first came out, he rejected the drug because it was what he called an orphan drug; meaning it was new and unproven, even though it was being injected everywhere. In 1997 - 1998, DR. KLEIN developed a five (5) point injection technique, which ALLERGAN later adopted. DR. KLEIN entered into a consultant agreement with ALLERGAN from May 1, 2004 to April 30, 2007.

ALLERGAN consultants would meet in Los Angeles, California. This includes [REDACTED] LNU (Last Name Unknown), [REDACTED]. These consultants would meet to determine who was going to speak at Continuing Medical Education (CME) events on the application of BOTOX. DR. KLEIN advised the purpose of these events was to create new injectors for off-label use for cosmetic purposes. DR. KLEIN helped introduce BOTOX to Asia, Europe and many other countries. The [REDACTED] were publishing articles in the United States (U.S.), yet they were not U.S. Citizens. Additionally, DR. KLEIN advised the [REDACTED] were traveling the U.S. and injecting patients, yet they were not licensed in the U.S. DR. KLEIN has a different approach to injecting BOTOX from the [REDACTED] approach. DR. KLEIN supported small amounts of BOTOX to be used, where the [REDACTED] supported large amounts to be used. DR. KLEIN advised that with as little as 60 units of BOTOX, the side affect of preventing swallowing can occur.

Investigation on 04/22/2008 at Los Angeles, CaliforniaFile # 209A-AT-102189-111Date dictated 04/28/2008by SA [REDACTED]
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DR. KLEIN was promised by ALLERGAN that he would be their chief filler physician. DR. KLEIN described fillers as substances that were injected under the skin to remove wrinkled areas. In 2003, an article came out about fillers and the [redacted] became the chief ALLERGAN consultants,

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DR. KLEIN was asked to review an BOTOX article, which was originally titled, "Dilution Volume of Botulinum Toxin Type A for the Treatment of Glabellar Rhytides: Does it Matter?" After reviewing the study, DR. KLEIN rejected the study because he found that the graph showed that the wrinkles appeared to get worse after injections from the baseline data and he did not feel the study's population was large enough, in that, one (1) patient equaled 5 percent of the population. This study was released again years later and DR. KLEIN advised the graph did not appear in its entirety. Rather, the baseline data was removed, thus creating a positive study. DR. KLEIN contacted the editor, BILL COLEMAN, for the article with his concerns and he was told that he (COLEMAN) would take care of it. DR. KLEIN advised the article was later published without the baseline data, with a seven (7) point injection technique and it was under the [redacted] names, who were ALLERGAN's chief consultants. DR. KLEIN advised that COLEMAN now denies having communications with him, but DR. KLEIN advised he has maintained e-mails which document these communications.

DR. KLEIN advised there was another incident where there was false data related to articles. DR. KLEIN explained it was related to the article, "Dose-Finding, Safety, and Tolerability Study of Botulinum Toxin Type B for the Treatment of Hyperfunctional Glabellar Lines" by [redacted]

[redacted] According to DR. KLEIN, with MYOBLOC Type B there can be distant effects; meaning if it is injected in the head, a patient can have trouble swallowing. DR. KLEIN's name was put on the article and DR. KLEIN did not agree with the content of the study, nor did he believe there was adequate science to support that MYOBLOC was safe and effective. According to DR. KLEIN, the publishing company, SOLSTICE, published the article and put his name on it. DR. KLEIN contacted the President of SOLSTICE, MAX LINK, who told him to contact DAVID PYOTT, ALLERGAN, Chief Executive Officer (CEO).

DR. KLEIN was very concerned about the articles so he met with PYOTT. DR. KLEIN told PYOTT that he could not work with the [redacted] because he felt they lied and were forging data in the studies, he questioned the articles being published and questioned

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the [redacted] being made the "Czars" for BOTOX. DR. KLEIN advised the [redacted] did not reveal in the articles to the FDA that they (the [redacted] were stockholders in the company (ALLERGAN.) DR. KLEIN provided PYOTT with the examples previously referenced. Specifically, DR. KLEIN showed PYOTT the graphs which showed that is may not be safe and effective. Further, DR. KLEIN reiterated that this article was funded by an unrestricted medical grant. PYOTT told him that he would look into it.

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A short time later, PYOTT told DR. KLEIN that he was not allowed to attend a CME program for fillers. DR. KLEIN advised he was up for his contract renewal with ALLERGAN and it was moving forward until he started voicing his concerns. DR. KLEIN kept trying to address the issue, but no one wanted to deal with it. ROBERT GRANT, President of ALLERGAN Aesthetics, asked him not to be a part of the executive counsel, but told him he could remain a consultant if he kept quiet. One month later, according to DR. KLEIN, he was let go by ALLERGAN.

DR. KLEIN remembered a CME that was held on March 13, 2008, at the BELLAGIO HOTEL in Las Vegas, Nevada. DR. KLEIN advised ALLERGAN had concerns about what DR. KLEIN was going to discuss prior to the speech, since it was shortly after the press release. The CME vendor was MILLENIUM and the two people in charge of the program were a husband and wife, [redacted]
[redacted]

DR. KLEIN advised over 700 newspapers have picked up his story related to BOTOX and ALLERGAN's forgery of data. DR. KLEIN advised physicians that are not experts and rely on the data that is in journals to assist in treating their patients. If this data is not accurate, then the patients are at risk. DR. KLEIN advised he wants to bring science back to medicine, instead of it being directed by sales. Further, non-specialist physicians are being trained to inject for cosmetic purposes, but they will inject for everything. DR. KLEIN again advised the CMEs are discussing off-label uses for BOTOX.

DR. KLEIN was asked who else would have knowledge of ALLERGAN's off-label promotion and he provided the following names:

[redacted]

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At the conclusion of the interview, DR. KLEIN and his attorney [] agreed to provide copies of the supporting documents that were discussed in this interview. These documents were later mailed via Federal Express and received by AUSA [] AUSA [] will maintain these documents at the U.S. Attorneys Office, Northern District of Georgia.

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